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Exhibit 470

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ATTORNEY WORK PRODUCT
DRAFT OF 10.19.2017

ANTI-DIVERSION INDUSTRY WORKING GROUP PETITION FOR NOTICE-AND-COMMENT RULEMAKING REGARDING SUSPICIOUS ORDER MONITORING

Pursuant to 5 U.S.C. § 553(e), members of the Anti-Diversion Industry Working Group ("Petitioners" or "ADIWG") hereby petition the Drug Enforcement Administration ("DEA" or the "Agency") for notice-and-comment rulemaking to establish clear, effective and workable rules regarding the duty to monitor and report suspicious orders for controlled substances.

EXECUTIVE SUMMARY

As the Agency is aware, the United States faces an unprecedented epidemic of opioid addiction and abuse. The problem defies easy solution. A comprehensive response must address the challenges surrounding physician prescribing habits, supply chain safeguards, law enforcement efforts, addiction treatment, and, ultimately, the development of safe and effective non-opioid alternatives for the treatment of pain. Any solution must also balance the rights of patients to obtain necessary medication with the risk that individuals seeking to break the law will divert those medications from their legitimate purpose.

No agency or organization can solve the problem alone. Government regulators, policymakers, law enforcement, manufacturers, distributors, physicians and pharmacists must work together to address the complex causes of prescription drug diversion and abuse. Those efforts must be coordinated and reflect the realities of the supply chain. That starts with clearly defining the parties' respective roles and responsibilities.

The Agency is uniquely situated—and required by law—to define the responsibilities of those in the opioid supply chain. Although DEA has, in recent years, begun to engage more productively with industry, it has yet to provide clear, consistent and workable rules regarding DEA registrants' anti-diversion obligations. That shortfall has been particularly acute with respect to registrants' duty to monitor and report suspicious orders under 21 C.F.R. 1301.74(b) (the "SOM Regulation").

Moreover, the Agency has attempted to announce new, ill-advised obligations through informal channels, in circumvention of the Administrative Procedure Act ("APA"). By avoiding the notice-and-comment process, the Agency has forgone the critical input of those on the front line of fighting diversion—DEA registrants—and attempted to impose a fundamentally unsound system of un-vetted and conflicting "rules." That has left registrants in the untenable position of trying to interpret and implement DEA's increasingly burdensome and incongruous demands or to focus their efforts on more effective avenues of detecting and preventing diversion of opioids.

To take one example, DEA has issued inherently inconsistent guidance regarding the algorithms many registrants use to assist in detecting suspicious orders. In one published Agency manual, DEA stated that computer algorithms are "the only viable, cost effective methodology" for detecting suspicious orders. Then, in 2006, DEA sent letters to registrants stating that reporting the results of internal algorithms did not fulfil a registrant's obligation to

detect and report suspicious orders. More recently, DEA has suggested that registrants must report to DEA all orders identified by internal compliance algorithms, even though they are not suspicious. Not only does that position clearly depart from previously announced agency positions, it ignores the express preferences of DEA diversion investigators in the field, who have little use for over-inclusive internal company reports.

These new "rules" and others like them plainly violate the APA, which requires new substantive rules to be promulgated through notice-and-comment rulemaking. *See infra*. Moreover, because they seem to have been informally "adopted" without benefit of input by those affected, these un-promulgated, unclear and at times conflicting rules create conflicting and burdensome obligations that serve little practical purpose, diverting registrants' resources from other efforts that more effectively fight diversion. And even as this regulatory incoherence is undermining the fight against diversion, it also leaves industry participants exposed to enforcement actions and demands for civil penalties based on "rules" that have never been properly adopted, or even clearly stated. This state of affairs is unsustainable and does not advance the goals of the SOM Regulation.

Petitioners believe we can do better. ADIWG is a collection of DEA registrants who are committed to fighting opioid diversion and abuse. They consist of prominent, publicly traded companies in the pharmaceutical industry that have, for several years, proactively engaged in efforts to curb the problem of opioid addiction and abuse.[1] Petitioners are committed to partnering with DEA in its fight against diversion, but believe DEA must promulgate clear and sensible rules for industry to follow. Accordingly, the undersigned submit this petition to request that the Agency engage in notice-and-comment rulemaking to establish clear, consistent, effective and workable rules regarding registrants' obligation to monitor and report suspicious orders for controlled substances.

FACTUAL BACKGROUND

The SOM Regulation requires registrants to "design and operate a system to disclose to the registrant suspicious orders" of controlled substances and "inform the Field Division Office of the Administration in his area" of those orders. 21 C.F.R. 1301.74(b). Since DEA promulgated the regulation in 1971, the language of the regulation has remain unchanged.

<u>DEA Reverses Its Position on Order Algorithms & Investigation Before Shipment</u>

Until 2006, the only written guidance from DEA regarding suspicious order monitoring was an appendix to the Agency's 2004 Chemical Handler's Manual. The appendix was drawn from a 1998 report adopted by a suspicious order monitoring task force mandated by Congress and recommended a six-step "voluntary" computer algorithm to analyze orders submitted to a registrant. The Manual stated that using such a computer algorithm was "the only viable, cost effective methodology" for suspicious order reporting. U.S. Dept. of Justice, *Chemical Handler's Manual: A Guide to Chemical Control Regulations* (Jan. 2004).

[1] [Members]

The Agency attempted to reverse that position in 2007. In a letter to registrants, a DEA deputy assistant administrator wrote that "[r]egistrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders." Letter from Joseph T. Rannazzisi, DEA, Deputy Assistant Administrator, to Registrant (Dec. 27, 2007). The Agency warned that "DEA does not approve or otherwise endorse any specific system for reporting suspicious orders. Past communications . . . that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system." *Id.* The Agency offered no further guidance in connection with this abrupt reversal.

In a similar letter written in 2006, DEA similarly attempted to institute an entirely new rule requiring registrants must *investigate* suspicious orders, rather than simply report them as required by the SOM Regulation. The 2006 letter outlined questions to consider in determining whether a suspicious order was indicative of diversion" and thus should not be shipped. *Id.* This language plainly implied a difference between an order that was "suspicious" and an order that was "indicative of diversion," with the latter being a subset of the former. Yet the letter gave no explanation of the source of the additional obligation

The following year, a similar letter echoed the Agency's new position that "[r]egistrants must conduct an independent analysis of suspicious orders prior to completing a sale." Letter from Joseph T. Rannazzisi, DEA, Deputy Assistant Administrator, to Registrant (Dec. 27, 2007). Again, the Agency offered no support for these unprecedented investigative obligations. Nor, of course, had the Agency undertaken any public process to give notice of or solicit input on these regulatory changes before they were announced.

The changes outlined in the informal 2006 and 2007 letters were a significant shift in DEA policy. As Kyle Wright of DEA's Office of Diversion Control confirmed in sworn testimony in 2011, the new investigative and halt-shipment requirements were a "significant change" to registrants' obligations. Wright also testified that, until the change in policy, "DEA was aware that it was standard practice in the industry to file suspicious order reports while continuing to ship products, and that practice had been approved by the DEA." Trial Transcript, *United States v. Four Hundred Sixty Three Thousand Four Hundred Ninety Seven Dollars and Seventy Two Cents ($463,497.72), et al.*, No. 08-11564 (E.D. Mich. Aug. 12, 2011) at 382:24-383:18.

Even more recently, the Agency again took an incongruous position, indicating that every order triggering a flag in a registrants' suspicious order monitoring program is, by definition, suspicious and must be reported. *See* 80 Fed. Reg. 55,418, 55,501 (Drug Enforcement Administration, Docket No. 13-39, Masters Pharmaceuticals, Inc; Decision and Order); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206 (D.C. Cir. 2017). That position ignores the fact that the algorithms used in suspicious order monitoring programs are not uniform; they are often custom-built and can be calibrated to be "over-inclusive"—*i.e.*, to identify orders that might warrant a closer look, but may not actually be suspicious. It also ignores views of DEA diversion investigators in the field, who have repeatedly indicated to registrants that the output of internal company algorithms are not useful to them.

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DEA Announces New, Invalid Manufacturer Obligations via Press Release

This was not the only time the Agency used informal channels to announce dramatic changes to what it maintains registrants are obligated to do. In July 2017, DEA attempted to announce an entirely new—and invalid—suspicious order monitoring obligation for manufacturers.

Since DEA promulgated the regulation in 1971, DEA registrants have understood the SOM Regulation to require each level in the distribution chain to monitor and report suspicious orders received from the level below it. That is, manufacturers must monitor distributors, and distributors must monitor pharmacies. The industry operated under that understanding for more than forty-five years. At no time during the intervening decades did the Agency announce that the SOM Regulation required manufacturers to monitor or report orders placed to third-parties.

Between 2007 and 2014, DEA announced numerous settlements with registrants regarding alleged failures to report suspicious orders. All involved orders placed directly to the registrant. None of those settlements suggested any duty to monitor orders placed to third-parties downstream in the distribution chain. Although there has been no change to the operative regulation, DEA now asserts the opposite, contending that registrants who fail to monitor their "customers' customers" violate the 45-year-old rule.

DEA's announcement of a new duty to monitor third parties appears rooted, in part, on the Agency's misconception of a common pharmaceutical pricing mechanism called "chargebacks." A chargeback is a contractual payment from a manufacturer to a distributor made when a distributor has sold the manufacturer's product to a downstream customer at a price below a contractually mandated price in the distributor's contract. In essence, chargebacks make the distributor whole on their sales of the manufacturer's products. When the distributor sends its requests to the manufacturer for the payment of a chargeback, it provides information about the downstream sale to support the request.

While chargebacks provide the manufacturer a narrow glimpse into the distributor's downstream sales activity, that information is both incomplete and untimely. Not all sales result in chargebacks, and chargebacks can only occur after the manufacture has sold a product to a distributor - where the product can sit in the distributor's inventory for weeks or months - and the distributor has, in turn, sold the product to a downstream customer, such as a pharmacy. Moreover, chargebacks only provide information on the manufacturers' products sold by a particular distributor to a particular downstream pharmacy, painting an incomplete picture of the downstream pharmacy's purchases of controlled and non-controlled medications, which may be manufactured by other manufacturers and supplied by multiple distributors.

At an industry conference in 2015, a DEA representative announced—for the first time publicly, as far as Petitioners are aware—that manufactures should "do something" with the data that is collected in the course of the chargeback process. The Agency offered no meaningful explanation or further guidance regarding what that "something" should constitute. What uses manufacturers were then making of the information reflected the inherent limitations of the data; they did not include any attempt to identify and report individual downstream orders between

third parties. Only in July 2017, did the Agency publicly suggest, for the first time in the entire history of the SOM Regulation, that registrants should use chargeback data to monitor downstream transactions.

DEA's latest pronouncement on these issues came in a July 2017 press statement accompanying a settlement. On July 11, 2017, a manufacturer and ADIWG member, Mallinckrodt LLC, entered into a civil settlement agreement with the Agency to end a six-year investigation into Mallinckrodt's SOM program prior to 2012. As part of the agreement, Mallinckrodt committed to maintaining two different monitoring programs. First, it agreed to "design and operate a [suspicious order monitoring] system that meets the requirements of 21 C.F.R. 1301.74(b)"—a program that had already been in place for many years. *See* Agreement at 4 ("Reporting of Suspicious Orders"). Separately, it agreed to monitor chargeback data and "report to the DEA when [the manufacturer] concludes that chargeback data or other information indicates that a downstream registrant poses a risk of diversion"—a separate, proactive program that was similarly already in place for several years. *See* Agreement at 5 ("Chargeback Data Monitoring"). Specifically, the Chargeback Data Monitoring undertaking provides for the retrospective monitoring of a distributor's aggregate sales information and the reporting of any outlier *pharmacies* for further investigation by the Agency. This provision does not obligate Mallinckrodt to report as suspicious under the SOM Regulation downstream *orders* placed to distributors by pharmacies, nor could any manufacturer make such an undertaking. Manufacturers simply do not have the information necessary to be able to report downstream suspicious orders to which it is not a party.

While the settlement agreement carefully limited Mallinckrodt's obligations, the Department of Justice press release announcing the settlement mischaracterized the agreement's terms, seemingly in an attempt to use the document effectively to revise the SOM Regulation to impose a requirement on manufacturers to monitor and report suspicious downstream transactions between distributors and pharmacies. The statement touts "[t]he groundbreaking nature of this settlement [as] requiring a manufacturer to utilize chargeback and other similar data to monitor and report to DEA suspicious sales of its oxycodone at the next level in the supply chain, typically sales from distributors to independent and small chain pharmacy and pain clinic customers." *See* Dept. of Justice Press Release (July 11, 2017).[2] Beyond being inconsistent with the actual language of the settlement agreement, the press release is remarkable for the fact that it blatantly acknowledges that the Agency was attempting to impose a "groundbreaking"—in fact, unprecedented—"requir[ement]" to report suspicious orders "at the next level of the supply chain," without going through the steps mandated by the APA to adopt such a rule.

Notably, there is an inherent contradiction in the Agency's new asserted requirement to investigate suspicious orders before shipping—see above—and its new "rule" characterizing chargebacks as signaling suspicious orders. If the essence of the monitoring rule is that registrants must identify and investigate suspicious orders before shipment, then chargeback monitoring must necessarily be separate and apart from that requirement. By their nature,

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[2] Available at [HYPERLINK "https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders"]

chargebacks can only be reviewed after the transactions in question have already taken place. It is precisely this type of regulatory incoherence that the notice-and-comment process would help avoid.

DEA registrants now face ill-conceived and contradictory Agency positions divined from informal letters, industry conferences, individual company communications with DEA personnel, and enforcement actions. None has benefited from the procedural and substantive protections of notice-and-comment rulemaking. DEA's approach has only violated the APA; it has also diverted registrants' time and resources from more effective means of combatting illicit activity.

LEGAL STANDARD

Where, as here, an Agency seeks to impose new substantive obligations, it must promulgate those rules through the notice-and-comment rulemaking, providing opportunity for input from regulated parties.

The APA prohibits agencies from arbitrarily imposing new rules on regulated entities. *See Elec. Privacy Info. Ctr. v. U.S. Dep't of Homeland Sec (EPIC)*, 653 F.3d 1, 7 (D.C. Cir. 2011). All "legislative" rules must undergo the formal notice-and-comment rulemaking process before implementation. 5 U.S.C. § 553(e). A rule is legislative if it "effects a substantive change in existing law or policy," such as by "adopt[ing] a new position inconsistent with existing regulations." *Mendoza v. Perez*, 754 F.3d 1002, 1020-21 (D.C. Cir. 2014); *see also Batterton v. Marshall*, 648 F.2d 694, 701-02 (D.C. Cir. 1980) (defining legislative rules as those which "grant rights, impose obligations, or produce other significant effects on private interests"). Where an agency issued its original legislative rule through notice-and-comment, the agency must undertake notice-and-comment rulemaking to issue subsequent changes to the substance of that rule. *See Perez v. Mortgage Bankers Ass'n*, 135 S. Ct. 1199, 1206 (2015) (explaining that § 1 of the APA "mandate[s]" that agencies use the same procedures when they amend or repeal a rule as they used to issue the rule in the first instance"); *Am. Fed'n of Gov't Emps. v. Fed. Labor Relations Auth.*, 777 F.2d 751, 759 (D.C. Cir. 1985) ("[A]n agency seeking to repeal or modify a legislative rule promulgated by means of notice-and-comment rulemaking is obligated to undertake similar procedures to accomplish such modification or repeal."). The DEA in particular has previously used notice-and-comment rulemaking to amend regulations. *See* Schedules of Controlled Substances: Removal of Naldemedine From Control, 82 Fed. Reg. 132 (proposed July 12, 2017) (noting that the proposed rule stems from the DEA's granting of a petition "requesting that the DEA amend" an earlier regulation).

The rulemaking process serves two important functions: providing affected parties the opportunity to comment on proposed changes, and requiring agencies to articulate explanations for departing from their established view. *See, e.g.*, *Shands Jacksonville Medical Center v. Burwell*, 139 F. Supp. 3d 240, 365 (D.C. Cir. 2015) (explaining "the APA [] require[s] the disclosure of assumptions critical to the agency's decision, in order to facilitate meaningful comment and allow a 'genuine interchange' of views") (internal citation omitted); *Connecticut Light & Power Co. v. Nuclear Regulatory Comm'n*, 673 F.2d 525, 528 (D.C. Cir. 1982) ("One particularly important component of the reasoning process is the opportunity for interested parties to participate in a meaningful way in the discussion and final formulation of rules . . . An

equally important component of the process of reasoned decision-making is the agency's own explanation for the rules it adopts.").

Here, the Agency announced vague new obligations that deviate so substantially from the requirements under the original SOM Regulation that the Agency has effectively created new legislative rules. For example, from 1971 until 2006, the Agency held out computer algorithms as "the only viable, cost effective methodology" for suspicious order reporting." U.S. Dept. of Justice, *Chemical Handler's Manual: A Guide to Chemical Control Regulations* (Jan. 2004) and did not require distributors to investigate or block shipments of suspicious orders flagged by an algorithm. Yet guidance letters issued in 2006 and 2007 indicated that computer algorithms touted in 2004 would no longer be sufficient and imposed prospective investigation and halt-shipment obligations never before articulated by the Agency. As such, the new policy "substantively affect[ed] the public to a degree sufficient to implicate the policy interests animating notice-and-comment rulemaking." *EPIC*, 653 F.3d at 6. The D.C. Circuit panel in *Walgreens* considered and seemed persuaded that the new "investigate before shipment" requirement was not covered by existing regulations and therefore required notice-and comment-rulemaking. *See* Transcript of Oral Argument at 13-15, *Walgreen Co. v. Drug Enforcement Administration*, No. 12-1397 (D.C. Cir. Mar. 21, 2013). The panel did not issue a ruling, however, because Walgreens and DEA settled following oral argument.

DEA's decision in *Masters* raises the same concerns. The decision implies registrants must send the Agency their internal reports, even for orders that were simply flagged by an algorithm but not truly "suspicious" within the plain text meaning of the regulation. *See* 80 Fed. Reg. 55,418, 55,501 (Drug Enforcement Administration, Docket No. 13-39, Masters Pharmaceuticals, Inc; Decision and Order); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206 (D.C. Cir. 2017). Through the *Masters* case, DEA bypassed notice-and-comment rulemaking and significantly intensified registrants' reporting burden through enforcement, without any prior notice. *See Marseilles Land & Water Co. v. Fed. Energy Regulatory Comm'n*, 345 F.3d 916, 920 (D.C. Cir. 2003) ("For an administrative agency may not slip by the notice-and-comment rule-making requirements needed to amend a rule by merely adopting a de facto amendment to its regulation through adjudication."). Imposing a burdensome requirement that will inundate local agents with voluminous notices of not-really-suspicious orders seems far better calculated to create opportunities to seek massive civil penalties than truly to generate useful data.

Other Agency announcements suffer from the same infirmity. For example, before issuance of DOJ's July 2017 press release announcing its settlement with Mallinckrodt, the Agency never publicly indicated that manufacturers must monitor and report suspicious downstream transactions to which the manufacturer is not a party. By suggesting that manufacturers are required to monitor and report downstream sales from third-party distributors to third-party pharmacies, the press release heralded a "new position inconsistent with existing regulations." Even DOJ acknowledged that DEA was in uncharted territory, calling the settlement "groundbreaking." It further conceded that the settlement merely "advance[d]" the DEA's "*position* that controlled substance manufacturers need to go beyond 'know your customer' to use otherwise available company data to 'know your customer's customer.'" Advancing a position is not rulemaking. After forty-five plus years of monitoring *customers*, a

demand that manufacturers begin monitoring their "customer's customer" is "a substantive change in existing law or policy." *Mendoza*, 754 F.3d at 1025. Notice-and-comment is thus required. *Id.* (describing new regulatory interpretations published in agency guidance letters as legislative rules requiring notice and comment "because [the letters] change the regulatory scheme").

CHALLENGES AND PRINCIPLES GOING FORWARD

The lack of binding, formal rules on these issues presents significant challenges for registrants. Today, we wish to share a sample of the challenges registrants face and propose some principles for rulemaking going forward. Petitioners submit that these issues and others should be addressed though notice-and-comment rulemaking, through which the regulated community and other stakeholders help ensure that any final rule is both effective and practicable.

Examples of Current Challenges

DEA's guidance regarding the use of algorithms is inconsistent.

DEA has alternately taken the position that computer algorithms are "the only viable, cost effective methodology" for suspicious order monitoring (see the 2006 Chemical Handler's Manual) or that they are insufficient (see DEA's letters from 2006 and 2007). The Agency has also suggested both that orders should be investigated before shipment (see letters) and that all orders flagged by an algorithm should be reported regardless of investigation (see *Masters*).

DEA's 2006 and 2007 letters to registrants take the position that the regulation requiring "effective controls" against diversion requires registrants not to ship "suspicious" orders unless any investigation indicates the orders are not "likely" to indicate diversion. But DEA has provided no meaningful guidance to allow companies to distinguish between "suspicious orders" and those likely to result in diversion. That leaves registrants in a catch 22: they can either (a) report as "suspicious" every order flagged by an internal algorithm, but run the risk that DEA will later accuse the registrant of "shipping suspicious orders" they did their best to investigate, or (b) report only orders deemed to be suspicious following investigation, and risk DEA accusing the registrant of under-reporting, for failing to report all orders flagged by its internal algorithm.

Troublingly, DEA refuses to respond to the industry's requests for guidance on this issue. For example, at least one member of the ADIWG has asked DEA to clarify registrants' investigation and shipping obligations. The registrant received no response. DEA even stopped holding registrant conferences for several years, further limiting communication with the industry. When the conferences eventually resumed, registrants again tried to engage the DEA with questions about their monitoring and reporting duties. DEA again declined to clarify suspicious order monitoring obligations.

Manufacturers are not well positioned to monitor and assess individual downstream orders from third-party pharmacies to third-party distributors.

Monitoring and reporting suspicious orders from *direct customers* requires sophisticated algorithms, an understanding of the customers' business, and a team to investigate red flags. Monitoring and reporting individual orders placed *between third-parties* is nearly impossible. Simply put, manufacturers do not possess the data necessary to monitor individual downstream transactions between third-party pharmacies to third-party distributors to which the manufacturer is not a party. Once a manufacturer sells its product to the distributor and title transfers, the manufacturer lacks visibility and control; responsibility is effectively passed to the next DEA registrant in the supply chain.

Even if a manufacturer receives chargeback data later that allows it to identify orders placed to a distributor customer after the fact, it would be extremely difficult, if not impossible, for the manufacturer to gauge whether such orders are suspicious. Chargeback data necessarily reflect only orders of the manufacturer's product. The data do not include information about products made by other manufacturers or any given pharmacy's mix of controlled and non-controlled products, which is a key factor in assessing risk at the pharmacy level. *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Administrator, DEA (Sept. 27, 2006). For example, a pharmacy may purchase from a distributor a generic medication made by Manufacture A in one month and the same medication made by Manufacturer B the next. Manufacturer B may register an increase in volume in its chargebacks in the second month, but lack the context necessary to determine whether that "increase" is an increase in the pharmacy's orders at all—much less whether it is suspicious.

Even information about a manufacturer's own product is imperfect. Not all distributor sales are eligible for chargebacks, and when they are, distributors may wait days before reporting them. Regardless of the distributor's delay in submitting the chargeback request, in every instance, the downstream "order" is no longer an order. It is a completed sale, which DEA announced in December 2006 it no longer wanted to be reported. There is no reason to require manufacturers to engage in this empty exercise—it is unlikely to capture potential diversion that is not already captured by distributors, and certainly cannot identify a possible diversion before the shipment takes place. Distributors are far better positioned to monitor pharmacy orders while they are still "orders," indeed they are already required to do so, and have developed sophisticated SOM programs for that purpose.

Finally, Petitioners note that to the extent any party is well positioned to monitor the entire distribution chain, it is DEA. DEA is the only party with information regarding every legal sale of opioid products. As the Agency knows, manufacturers and distributors are required to report each sale of Schedule II and III products to DEA. *See* 21 C.F.R. 1304.33. Details of those transactions are stored in DEA's Automation of Reports and Consolidated Orders System (ARCOS) database. That database—which unlike registrants' information, provides complete visibility across manufacturers and distributors—can be mined for trends in ways that the more segmented and limited information available to registrants cannot. In fact, the DEA's own Targeting & Analysis Unit is tasked with manipulating and utilizing this comprehensive distribution chain data. It remains unclear to registrants whether and how their more limited SOM reports are used, much less why more burdensome requirements to produce less valuable reports are warranted.

There is no clear rule regarding obligations to monitor downstream transactions.

Manufacturers are currently struggling to determine how to meet DEA's vaguely announced expectations about monitoring downstream transactions. Many will likely employ some sort of algorithm based on partial data that, while imperfect, may generate a report that can be delivered to DEA. But discussions with registrants as well as with DEA diversion investigators suggest that those reports are of little use, precisely because they are over-inclusive. Counter-productively, they divert substantial resources that could be focused on more effective anti-diversion efforts, such as monitoring direct customers and mining the comprehensive ARCOS database. In sum, it makes little sense for manufacturers to attempt monitoring and reporting orders from pharmacies with which they have no contact—using only a fraction of the necessary information—when distributors are already monitoring, investigating, and reporting the same orders, and can do so in a much more targeted fashion that avoids burdening investigators with voluminous data that is already sitting in the ARCOS database.

Distributors are also left wondering about the implications of DEA's directive to "know your customers' customer" for other members of the supply chain. Does DEA mean to suggest that distributors located in far-off states should somehow monitor whether patients appearing at local pharmacies (*i.e.*, distributors' "customers' customers") are legitimate? Are they to re-evaluate the decisions of prescribing physicians in treating their patients? Are they to second-guess pharmacists in the carrying out of their corresponding responsibility under 21 U.S.C. § 829? Such an approach would of course be wasteful and ineffective. Yet, DEA's history of announcing, often after the fact, new interpretations of its vague standards makes it impossible for distributors to know the extent of their obligations.

Principles for a Workable Regulatory Scheme

As discussed above, one of the reasons the APA requires an agency to undertake notice-and-comment proceedings before adopting a new legislative rule is because that process leads to better informed, and thus substantively improved, regulations. Petitioners are committed to working closely with the Agency as it develops new rules in this area. Petitioners value collaboration and look forward to the exchange of ideas that comes through formal notice-and-comment rulemaking and increased informal dialogue. The following principles exemplify the type of contributions that Petitioners and others could add as the Agency considers proposed new rules through the rulemaking process:

1. **Clarity**. It is imperative that the Agency clarifies the term "suspicious order" and resolves the inconsistent guidance with respect to computer algorithms.

- *Define "suspicious order."* The term "suspicious order" has been at the heart of numerous multi-million dollar settlements, but its meaning remains unhelpfully and unnecessarily obscure. Petitioners recognize the necessity of a definition that adapts to changing circumstances. But to date, the ill-defined standard has served only to bolster DEA's litigation when it seeks to impose penalties; it has done little to ferret out orders that are actually suspicious – and clearly that is not the intent behind the SOM Regulation. Petitioners therefore request a clear and workable definition of "suspicious order" as part of a new rule or detailed interpretive guidance.

- *Set algorithm standards.* With no guidance on what constitutes a "suspicious" order, DEA registrants currently employ a patchwork of algorithms of varying degrees of sophistication. Without consistent, sophisticated standards across the industry, registrants may inundate DEA field offices with useless "suspicious order" reports or fail to identify orders that are truly indicative of diversion. Petitioners therefore request concrete standards for suspicious order algorithms as part of a new rule. Moreover, any new rule should make clear when to report orders that are flagged by the algorithm and what steps, if any, would permit registrants to fill such an order.

2. **Increased Collaboration**. Petitioners are committed to working together with DEA to combat the problem of drug diversion and abuse. Although Petitioners are encouraged by DEA's recent efforts to engage more productively with industry, the Agency must take additional steps to establish a genuine dialogue with registrants during the rulemaking process and going forward. The inconsistency and uncertainty surrounding registrants' obligations engendered by the Agency's historical lack of communication arguably has weakened the security of the substances supply chain. The Agency must engage a meaningful dialogue about its directives and how they are to be implemented. DEA and Petitioners share the common goal of combatting diversion, and each has a perspective, as well as tools and expertise, that can benefit the other. Petitioners suggest that the Agency consider, as it contemplates new proposed rules, a formalized process by which registrants can seek binding advisory opinions from the DEA that will allow them to adopt policies that are both workable and meet DEA's regulatory requirements.

3. **Acknowledgement of Differences within Supply Chain**. Petitioners request that any new rule separately identify the obligations of manufacturers and the obligations of distributors. The current regulation fails to distinguish between manufacturers and distributors and ignores the differences in the information available to each. Enforcement actions and Agency guidance referencing one type of registrant results in incongruity for the other. For example, some DEA letters released in 2006 and 2007 were addressed to distributors only or manufacturers only, with no corresponding guidance for other supply chain participants. A new rule should tailor regulatory obligations to the differences between entities at each level in the supply chain and create a set of clear standards for each.

CONCLUSION

For the foregoing reasons, Petitioners respectfully request that the Agency initiate notice-and-comment rulemaking to consider amendments to 21 C.F.R. 1301.74(b) that would replace the procedurally improper regulatory amendments the agency has sought to adopted through letters and press releases, as described above, with clear and legally binding rules that meaningfully contribute to the goal of reducing diversion and abuse of opioids and other controlled substances.